REMARKS

Reconsideration of this application and reexamination of the claims in view of the amendments herein are respectfully requested.

Status of the Claims

The listing of claims cancels claims 25, 83, 84, 92, and 103, and amends claims 24, 40, 91, and 101. Support for the claim amendments is found, for example, at paragraph 051 of the specification. No new matter is introduced by amendment.

Claims 24, 27-29, 31-34, 36, 40, 81, 82, 91, 94-96, 98-102, 104, 105, 110, and 111 are pending. Of those, claims 81, 82, 104, and 105 are withdrawn from consideration as drawn to non-elected inventions. Applicants request rejoinder of the withdrawn claims, once the independent claims are found allowable.

Information Disclosure Statement

Applicants submitted an Information Disclosure Statement and Form SB/08 on April 13, 2006. No initialed SB/08 Form was attached to the Office Action mailed June 26, 2006. Applicants courteously request that the Examiner consider the documents listed on that SB/08 Form and so indicate by initialing the Form at the appropriate locations and returning the Form to Applicants.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 24, 25, 27-29, 31-34, 36, 40, 91, 92, 94-96, 98-103, 110, and 111 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicants regard as the invention. Office Action at 3-4. The basis for this rejection is the Examiner's assertion that "DC-SIGN and DC-SIGN receptor are synonymous terms." According to

the Examiner, "[t]he acronym, 'DC-SIGN' does not include the term 'receptor'," so it is allegedly "unclear how a ligand (DC-SIGN) and its receptor (DC-SIGN receptor) can be one and the same."

Paragraph 051 of the specification states that, "[i]n the case of humans, 'DC-SIGN receptor' refers generically to DC-SIGN (described in Curtis et al., 2001), and/or DC-SIGNR (described in Pohlmann et al., 2001)." Applicants previously amended their claims to recite "DC-Specific ICAM-Grabbing Nonintegrin" immediately before the first use of the acronym "DC-SIGN," at the request of the Examiner. To ensure that the claims are even clearer, Applicants have now amended the claims to recite "human" and "one or more DC-SIGN receptor selected from DC-SIGN and DC-SIGNR." At the first use of each of those acronyms in the claims, Applicants wrote out the full name of each molecule, "DC-Specific ICAM-Grabbing Nonintegrin," and "DC-Specific ICAM-Grabbing Nonintegrin Related," respectively. Applicants submit that the claims particularly point out and distinctly claim the subject matter, which they regard as the invention, and submit that this rejection may be withdrawn. Applicants reserve the right to prosecute claims directed to additional subject matter, which they regard as their invention, in continuation or divisional applications.

Rejection Under 35 U.S.C. § 112, First Paragraph: Written Description

Claims 24, 25, 27, 29, 31-34, 40, 91, 92, 94, 96, 98-101, and 103 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Office Action at 5-6. According to the Examiner, "Applicant[s have] not demonstrated possession of a method that treats CMV or HIV wherein the molecule that binds DC-SIGN is any molecule other than those disclosed, such as mannan, Mab

1B10.2.6 and glycoprotein B." The Examiner expresses particular concern that Applicants have not demonstrated possession of a binding moiety of glycoprotein B or a generic antibody. Applicants respectfully traverse.

Regarding antibodies, the claims recite "wherein the molecule that specifically binds to the DC-SIGN receptor is an antibody." In some claims it is specified that the antibody is a monoclonal antibody or a humanized antibody. It is well established that disclosure of a protein and a statement in a specification that an invention includes antibodies that bind to that protein is sufficient to demonstrate possession of those antibodies such that the specification provides adequate support for those antibody claims under 35 U.S.C. § 112.

Specifically, in *Noelle v. Lederman*, 355 F.3d 1343, 1349 (Fed. Cir. 2004), the U.S. Court of Appeals for the Federal Circuit held that, "based on our past precedent, as long as an applicant has disclosed a '*fully characterized* antigen,' either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen." (Emphasis original.) The claims at issue in *Noelle* were directed to antibodies against CD40 counter receptor (CD40CR), a 30 kD protein. There is no mention in the decision that the particular amino acids within the antigen that form an epitope bound by any of the claimed antibodies were described or known in the art. Nonetheless, because of the wealth of information known in the art about antibody structure, the Federal Circuit in *Noelle* held that, by characterizing the protein antigen that an antibody binds to—at the protein level—an application demonstrates possession

of antibodies that bind to that antigen, sufficiently to satisfy the description requirement of § 112, first paragraph.

The *Noelle* court approvingly cited the Office's S*ynopsis of Application of Written Description Guidelines* ("*Synopsis*") in support of its holding. *Noelle*, 355 F.3d at 1349. In the *Synopsis*, the Office provides examples of disclosures and claims that together do or do not satisfy the written description requirement. (The *Synopsis* is available at http://www.uspto.gov/web/menu/written.pdf.) Example 16 deals with antibodies. Briefly, in the example the hypothetical specification teaches antigen X as purified by gel filtration and provides characterization of the antigen as having a molecular weight of 55 kD. The *Synopsis* example does not mention that the antigen X sequence is provided or known. The *Synopsis* example does describe that the hypothetical specification contemplates, but does not teach in an example, antibodies that specifically bind to antigen X, and asserts that these antibodies can be used in immunoassays. The hypothetical example does not, however, indicate that the application describes which amino acids in antigen X—the 55 kD protein—will be involved in antibody binding. However, in view of the wealth of knowledge known in the art regarding antibody structure, the Office concludes that a claim to an antibody capable of binding to antigen X is fully supported by that specification.

Applicants' claims recite methods of using antibodies that bind to the DC-SIGN receptor, a well characterized protein. Applying the standard articulated in *Noelle* and in the *Synopsis*, the Examiner can not credibly assert that Applicants' disclosure does not demonstrate possession of methods of using such antibodies in the methods as claimed.

Regarding the Examiner's concerns as to the claims directed to a binding moiety of glycoprotein B, Applicants have demonstrated possession of the claimed subject matter by demonstrating that binding of glycoprotein B to DC-SIGN inhibits CMV infection. (Application at paragraph 0147.) Glycoprotein B comprises a binding moiety of glycoprotein B and is thus an exemplary species. Applicants respectfully request that this rejection be withdrawn.

Finally, the Examiner is concerned that claims, such as claim 24, which recites "a molecule that specifically binds to the DC-SIGN receptor," are broader than the scope of written description. Applicants submit that they are claiming a method, and that they have shown in their specification the method can be practiced with any of various classes of compounds. The diversity of reagents that can be used reflects that the **method** is fully described. As such, Applicants have demonstrated to the skilled artisan that they possess the full scope of the methods as claimed.

For the foregoing reasons the rejection for lack of written description should be withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph: Enablement

Claims 24, 25, 27-29, 31-34, 36, 40, 91, 92, 94-96, 98-103, 110, and 111 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Office Action at 6-9. Specifically, the Examiner states that, "[t]he breadth of the claims is unreasonable, encompassing the inhibition of binding between the CMV and HIV virus and the mammal's dendritic cells, in a mammal already infected with the virus."

The standard for determining whether a specification meets the enablement requirement is whether the experimentation needed to practice the invention is undue or unreasonable. *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988); MPEP 2164.01. "[T]hat experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue." MPEP 2164.01 (internal citations omitted).

The Examiner appears to feel that the disclosure regarding results obtained *in vitro* provided by the specification will not be sufficient to allow the skilled artisan to practice the claimed invention *in vivo*. The Examiner states:

> The level of predictability in the art is low because the mechanism described in this invention is novel, and thus *in vivo* experimentation is required to determine whether *in vitro* results reflect *in vivo* performance. Competitive binding of dendritic cells is a complex mechanism. Extrapolating a competitive binding assay *in vitro* to an *in vivo* human treatment is not substantiated because the concept of using DC-SIGN receptor competitive binding for these two viruses is novel. One cannot predict the outcome of a new mechanism that has only been demonstrated *in vitro*. Treatment of HIV and CMV would indicate that there is a therapeutic benefit to administering a DC-SIGN receptor to a patient infected with HIV or CMV. Applicant has not demonstrated treatment of any sort.

(Office Action at 8.)

In response to the Examiner's characterization of uncertainty, Applicants note that making just such determinations is routine in the art. What is not routine, and what Applicants discovered, is the molecular mechanism of CMV viral entry. Armed with that information and the teachings of the specification, the skilled artisan can practice the invention as claimed. Applicants fully agree that in the ordinary course of doing so the

skilled artisan will apply well established techniques to determine what amount of a molecule that specifically binds to the DC-SIGN receptor is sufficient to inhibit the binding of the CMV virus effector molecule to the DC-SIGN receptor to thereby treat the CMV virus infection. Doing so will not require undue experimentation. The Examiner appears to suggest that finding such a dosage would be undue, but does not provide any rationale of why that would be so. Applicants submit that the skilled artisan could make just such a determination, first conducting further *in vitro* studies, then conducting studies in rodents, and ultimately conducting further studies in humans. That is the ordinary course of taking a discovery and commercializing it and is not undue experimentation.

Applicants need not prove beyond all doubt that their invention is commercially viable. Rather, Applicants specification must enable the skilled artisan to practice the invention as claimed without undue experimentation. *See* M.P.E.P. 2164 ("[T]o comply with 35 U.S.C. 112, first paragraph, it is not necessary to 'enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.' Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention." (Citations omitted)).

Applicants also note that claim 91 recites "[a] method of inhibiting entry of a CMV virus into a cell of a human that expresses one or more DC-SIGN receptor selected from DC-SIGN and DC-SIGNR of the human to be treated, the method comprising administering to the human a molecule that specifically binds to the DC-SIGN receptor." That method does not require a specific therapeutic outcome, but rather a mechanistic

outcome—viral entry is inhibited. The experiments reported in the specification show that this result is obtained using the methods disclosed. Thus, in addition to many variations enabled by the specification, the skilled artisan need only practice what is expressly disclosed in order to practice this invention. Therefore, claim 91, and claims 94-96, 98-102, 104, 105, and 111, which depend from claim 91, are all enabled for this additional reason.

Applicants respectfully request that the enablement rejection be withdrawn.

Conclusion

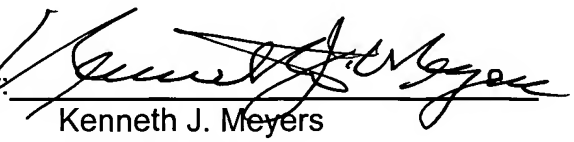
In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: September 26, 2006

By: 

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